

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 20, 2020

EIGER BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36183
(Commission
File Number)

33-0971591
(IRS Employer
Identification No.)

Eiger BioPharmaceuticals, Inc.
2155 Park Blvd.
Palo Alto, California 94306
(Address of principal executive offices, including zip code)

(650) 272-6138
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001	EIGR	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.01. Entry into a Material Definitive Agreement.

On November 20, 2020, Eiger BioPharmaceuticals, Inc. (the “Company”) entered into an asset purchase agreement (the “Agreement”) with AbbVie Inc. (“AbbVie”) to sell its Rare Pediatric Disease Priority Review Voucher (“PRV”) to AbbVie.

The Company was awarded the PRV on November 20, 2020 upon approval by the U.S. Food and Drug Administration of the Company’s new drug application for Zokinvy™ in Hutchinson–Gilford Progeria Syndrome and processing-deficient Progeroid Laminopathies.

In consideration for the PRV, AbbVie will pay the Company \$95.0 million upon closing of the PRV purchase. Such consideration received will be shared with The Progeria Research Foundation (“PRF”) in accordance with the terms of the Company’s Collaboration and Supply Agreement with PRF, dated May 15, 2018, pursuant to which the Company and PRF will equally share any proceeds from the sale of a priority review voucher that the Company may receive as the sponsor of a rare pediatric disease product application. The Company will retain approximately \$47.5 million of the proceeds.

The Agreement contains customary representations, warranties, covenants, and indemnification provisions subject to certain limitations. The transaction remains subject to customary closing conditions, including the expiration or termination of the required waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

The foregoing description of the Agreement does not purport to be complete and is subject to, and qualified in its entirety by reference to, the full text of the Agreement. The Company intends to file, with confidential terms redacted, a copy of the Agreement as an exhibit to the Company’s Annual Report on Form 10-K for the fiscal year ending December 31, 2020.

Item 2.01. Completion of Acquisition or Disposition of Assets.

The disclosure regarding the Agreement contained in Item 1.01 of this Current Report on Form 8-K is incorporated by reference into this Item 2.01.

Item 8.01. Other Events.

On November 23, 2020, the Company issued a press release announcing the Agreement, a copy of which is attached hereto as Exhibit 99.1 and incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.**(d) Exhibits.**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated November 23, 2020, titled “Eiger BioPharmaceuticals Sells Priority Review Voucher for \$95 Million.”
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: November 23, 2020

Eiger BioPharmaceuticals, Inc.

By: /s/ Sriram Ryali
Sriram Ryali
Chief Financial Officer

Eiger BioPharmaceuticals Sells Priority Review Voucher for \$95 Million

- *Eiger and The Progeria Research Foundation will share proceeds 50/50*
- *Non-dilutive capital further strengthens Eiger's balance sheet*

PALO ALTO, Calif., November 23, 2020 / PRNewswire / — Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), focused on the development and commercialization of targeted therapies for serious rare and ultra-rare diseases, today announced that it has entered into a definitive agreement to sell its Priority Review Voucher (PRV) for a lump sum payment of \$95 million. Eiger will retain fifty percent of the proceeds, or \$47.5 million, under the terms of the Collaboration and Supply Agreement with The Progeria Research Foundation (PRF).

The PRV was granted in conjunction with the recent approval by the U.S. Food and Drug Administration of Zokinvy™ (lonafarnib) for treatment of Progeria and processing-deficient Progeroid Laminopathies. The transaction remains subject to customary closing conditions, including anti-trust review.

“The sale of the PRV provides Eiger with an important source of non-dilutive capital and further strengthens our balance sheet. The proceeds allow us to continue to ensure that all diagnosed children and young adults worldwide with Progeria and processing-deficient Progeroid Laminopathies have access to Zokinvy and to advance our late-stage pipeline that now includes three breakthrough therapy designated programs,” said David Cory, President and CEO of Eiger. “We are proud that Zokinvy is our first approved product and the first approved therapy for children and young adults with Progeria and processing-deficient Progeroid Laminopathies.”

For full prescribing information, visit www.zokinvy.com.

About Zokinvy™ (lonafarnib)

Zokinvy blocks the accumulation of defective, farnesylated proteins which form tight associations with the nuclear envelope, leading to cellular instability and the process of premature aging in children and young adults with Progeria and processing-deficient Progeroid Laminopathies.

Eiger licensed exclusive worldwide rights to lonafarnib from Merck, known as MSD outside of the United States and Canada. Merck will not receive any milestone payments for the development of lonafarnib for the treatment of Progeria, and has waived royalty obligations from Eiger for a specified quantity of lonafarnib.

INDICATION

ZOKINVY is indicated in adult and pediatric patients 12 months of age and older with a body surface area (BSA) of 0.39 m² and above:

- To reduce the risk of mortality in Hutchinson-Gilford Progeria Syndrome (HGPS)
- For the treatment of processing-deficient Progeroid Laminopathies with either:
 - Heterozygous LMNA mutation with progerin-like protein accumulation
 - Homozygous or compound heterozygous ZMPSTE24 mutations

Limitations of Use

ZOKINVY is not indicated for use in patients with non-HGPS Progeroid Syndromes or with Progeroid Laminopathies known to be processing-proficient. Based upon its mechanism of action, ZOKINVY would not be expected to be effective in these populations.

Contraindications

- Strong or moderate CYP3A inhibitors or inducers
- Midazolam
- Lovastatin, simvastatin, and atorvastatin

IMPORTANT SAFETY INFORMATION

- The most common adverse reactions are vomiting (90%), diarrhea (81%), infection (78%), nausea (56%), decreased appetite (53%), fatigue (51%), upper respiratory tract infection (51%), abdominal pain (48%), musculoskeletal pain (48%), electrolyte abnormalities (43%), headache (37%), decreased weight (37%), increased aspartate aminotransferase (35%), myelosuppression (35%), cough (33%), decreased blood bicarbonate (33%), hypertension (29%), and increased alanine aminotransferase (27%).

Gastrointestinal Adverse Reactions

- Gastrointestinal adverse reactions were the most frequently reported adverse reactions. Of the 57 patients (90%) that experienced vomiting, 30 (53%) patients had mild vomiting, 26 (46%) patients had moderate vomiting, and 1 (2%) patient had severe vomiting.
- Of the 35 patients (56%) that experienced nausea, 34 (97%) patients had mild nausea and 1 (3%) patient had moderate nausea.
- Of the 51 patients (81%) that experienced diarrhea, the majority of patients (92%) experienced mild or moderate diarrhea; 38 (75%) patients reported mild diarrhea and 9 (18%) patients reported moderate diarrhea. Four (8%) patients reported severe diarrhea.
- Loss of fluids and dehydration can be severe, leading to hospitalization. As a result, patients should receive therapy for diarrhea at the earliest signs in order to avoid possible severe complications.

Alanine Aminotransferase and Aspartate Aminotransferase Elevations

- Increased alanine aminotransferase was commonly reported (17 [27%] patients). Of the 17 patients with increased alanine aminotransferase, 14 (82%) patients had mild increases, 1 (6%) patient had moderate increases, and 2 (12%) patients had severe increases.

- Increased aspartate aminotransferase was also commonly reported (22 [35%] patients). Of the 22 patients with increased aspartate aminotransferase, 21 (95%) patients had mild increases and 1 (5%) patient had a severe increase.

Hypertension

- Increases in blood pressure have been documented in patients treated with ZOKINVY. At baseline 22 (35%) patients had either a systolic blood pressure or a diastolic blood pressure or both above the 95th percentile. Over the course of the trials, 18 (29%) patients had hypertension based on systolic blood pressure or diastolic blood pressure measurements above the 95th percentile on 3 or more occasions. Five (8%) patients who were normotensive at baseline had either systolic blood pressure or diastolic blood pressure above the 95th percentile at the end of treatment.

Ophthalmic Adverse Reactions

- Lonafarnib caused retinal toxicity in monkeys at 3.7 times the human dose based on plasma drug exposure, but not at 2.1 times the human dose.

Laboratory Abnormalities

Some patients treated with ZOKINVY developed laboratory abnormalities. These included:

- Electrolyte abnormalities (43%), such as hyperkalemia, hypokalemia, hyponatremia, or hypercalcemia
- Myelosuppression (35%), such as reductions in absolute neutrophil count, white blood cell counts, lymphopenia, hemoglobin, or hematocrit
- Increased liver enzymes, such as aspartate aminotransferase (35%), or alanine aminotransferase (27%)

These laboratory abnormalities often improved while continuing ZOKINVY, but it is not possible to exclude ZOKINVY as a cause of the abnormalities. Periodically monitor electrolytes, complete blood counts, and liver enzymes, and manage abnormalities accordingly.

Nephrotoxicity

- Lonafarnib caused nephrotoxicity in rats at plasma drug exposures approximately equal to that achieved with the human dose. Monitor renal function at regular intervals during ZOKINVY therapy.

Retinal Toxicity

- Lonafarnib caused rod-dependent, low-light vision decline in monkeys at plasma drug exposures similar to that achieved with the human dose. Perform ophthalmological evaluation at regular intervals and at the onset of any new visual changes during ZOKINVY therapy.

Impaired Fertility

- Lonafarnib caused impaired fertility in female rats at 1.2 times the human dose based on plasma drug exposure.
- Lonafarnib caused impaired fertility and testicular toxicity in male rats at 1.5 times the human dose based on plasma drug exposure, and toxicity in the male reproductive tract in monkeys at doses lower than the human dose based on plasma drug exposure.

About Eiger

Eiger is a commercial-stage biopharmaceutical company focused on the development and commercialization of first-in-class, well-characterized drugs for serious rare and ultra-rare diseases for patients with high unmet medical needs.

Zokinvy for the treatment of Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and progerin-deficient Progeroid Laminopathies is the Company's first FDA approval. A Marketing Authorization Application (MAA) has been accepted and is under review by the European Medicines Agency (EMA). Outside the U.S., Eiger's established global Managed Access Program, expected to span greater than 40 countries, ensures all children and young adults with Progeria and Progeroid Laminopathies have access to treatment.

Eiger's lead clinical programs target Hepatitis Delta Virus (HDV) infection, the most serious form of human viral hepatitis. Eiger is developing two complementary treatments for HDV. Lonafarnib is a first-in-class, oral prenylation inhibitor in a global Phase 3 trial. Peginterferon lambda is a first-in-class, well-tolerated type III interferon entering Phase 3.

For additional information about Eiger and its clinical programs, please visit www.eigerbio.com

Note Regarding Forward-Looking Statements

This press release contains "forward-looking" statements that involve substantial risks and uncertainties. All statements other than statements of historical facts, including statements regarding our future financial condition, timing for and outcomes of clinical results, business strategy and plans and objectives for future operations, are forward-looking statements. These forward-looking statements include terminology such as "believe," "will," "may," "estimate," "continue," "anticipate," "contemplate," "intend," "target," "project," "should," "plan," "expect," "predict," "could," "potentially" or the negative of these terms. Forward-looking statements are our current statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our anticipating significant milestones in 2020 and 2021, the timing of our ongoing and planned clinical development, including our ability to support the launch of a new product and ship to specialty pharmacies; our

development programs for Zokinvy generally; and the potential approval of Zokinvy in jurisdictions outside of the U.S., including the EU; the risks related to the commercialization of Zokinvy, our ability to manufacture sufficient quantities of Zokinvy, and the commercial launch of Zokinvy in the U.S., the market potential for Zokinvy as a treatment for Progeria and processing-deficient Progeroid Laminopathies; our progression and enrollment of our Phase 3 D-LIVR study in HDV; our ability to maintain supply of our commercial and clinical trial materials; our plans to advance Lambda in HDV in the U.S. and EU; our ability to transition into a commercial stage biopharmaceutical company; our ability to finance the continued advancement of our development pipeline products; and the potential for success of any of our product candidates. These statements concern product candidates that have not yet been approved for marketing by the U.S. Food and Drug Administration (FDA). No representation is made as to their safety or effectiveness for the purposes for which they are being investigated. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Eiger makes, including additional applicable risks and uncertainties described in the “Risk Factors” sections in the Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 and Eiger’s subsequent filings with the SEC. The forward-looking statements contained in this press release are based on information currently available to Eiger and speak only as of the date on which they are made. Eiger does not undertake and specifically disclaims any obligation to update any forward-looking statements, whether as a result of any new information, future events, changed circumstances or otherwise.



SOURCE Eiger BioPharmaceuticals, Inc.

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